

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:

*The County of Summit, Ohio, et al. v. Purdue
Pharma L.P., et al.*, Case No. 18-op-45090

*The County of Cuyahoga, Ohio, et al. v.
Purdue Pharma L.P., et al.*, Case No. 17-op-
45004

MDL No. 2804

Hon. Dan Aaron Polster

DEFENDANTS' DAUBERT ROADMAP BRIEF

INTRODUCTION

Plaintiffs have engaged in a practice that “has become fashionable among some well-financed litigants—the engagement of ‘expert’ witnesses whose intended role is more to argue the client’s cause from the witness stand than to bring to the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit.” *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 538 (S.D.N.Y. 2004).

The proof is in the proposed opinions of Plaintiffs’ experts who seek to testify regarding irrelevant, unreliable, and speculative theories of causation, liability, and damages that facially violate Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). The experts also want to provide improper “narrative” testimony—their own spin on the documents and the parties’ supposed intent over which they have no personal knowledge—“merely tell[ing] the jury what result to reach.” *United States v. Kilpatrick*, 798 F.3d 365, 381 (6th Cir. 2015). The Court should reject Plaintiffs’ invitation to admit testimony that would constitute manifest and reversible error and jeopardize the integrity of the trial.

This brief is filed as Defendants’ “roadmap” on *Daubert* motions pursuant to Special Master Cohen’s Amended Order Regarding Pretrial Motions for Track One Trial, Dkt. No. 1709 (June 21, 2019), and provides an overview of Defendants’ accompanying motions to exclude this improper testimony. Part I identifies Defendants’ motions. Part II sets forth the governing legal standards relevant to those motions. And Part III provides a general overview of the core defects with the experts’ qualifications, opinions, and/or proposed evidentiary models, as described more fully in the individual motions.

I. DEFENDANTS' MOTIONS

Defendants¹ are filing the following motions to exclude Plaintiffs' proposed expert testimony relating to causation, liability, and damages:

CAUSATION
Motion to Exclude Expert Testimony of Meredith Rosenthal
Motion to Exclude Expert Testimony of David Cutler
Motion to Exclude Expert Testimony Regarding Plaintiffs' "Gateway" Hypothesis of Causation of Katherine Keyes, Anna Lembke, and Jonathan Gruber
Motion to Exclude Expert Testimony Regarding Marketing Causation of Mark Schumacher, Anna Lembke, and Katherine Keyes
Motion to Exclude Expert Testimony of Jonathan Gruber
LIABILITY -- MARKETING
Motion to Exclude Expert Testimony of David Egilman
Motion to Exclude Expert Testimony of David A. Kessler and Matthew Perri
LIABILITY -- DIVERSION
Motion to Exclude Expert Testimony of Seth Whitelaw
Motion to Exclude Expert Testimony of James Rafalski
Motion to Exclude Expert Testimony of Craig McCann
Motion to Exclude Expert Testimony of Lacey Keller
DAMAGES AND ABATEMENT
Motion to Exclude Expert Testimony of Thomas McGuire
Motion to Exclude Expert Testimony Regarding Abatement Costs and Efforts of Caleb Alexander, Jeffrey Liebman, Katherine Keyes, Scott Wexelblatt, Nancy Young, and Thomas McGuire

¹ On June 10, 2019, Insys Therapeutics, Inc. and its affiliates each filed a voluntary case under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, which are being jointly administered under Case No. 19-11292 (KG). In light of this bankruptcy proceeding, Insys does not join any of the *Daubert* motions or summary judgment motions to be filed in the MDL Track One cases. Because Noramco is only joining the *Daubert* motion on Dr. David Kessler, Noramco only joins this Motion to the extent it pertains to the opinions of Dr. Kessler. He is the only expert who mentioned Normaco specifically in the course of expert discovery.

II. GOVERNING LEGAL STANDARDS

A. The Court Is a Gatekeeper With a Special Obligation to Ensure Proffered Expert Testimony Satisfies Rule 702

Under Federal Rule of Evidence 702, trial courts serve a vital “gatekeeping role” and are responsible for “ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.” *Daubert*, 509 U.S. at 597. “[E]xpert evidence can be both powerful and quite misleading.” *Id.* at 595 (citation omitted). Thus, as the Sixth Circuit has repeatedly admonished, “because expert witnesses are not necessarily always unbiased scientists,” determining the admissibility of expert testimony requires “close judicial analysis.” *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 252 (6th Cir. 2001) (quoting *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1352 (6th Cir. 1992)). In conducting this threshold analysis, courts must exclude expert testimony that is not “based on sufficient facts or data,” is not “the product of reliable principles and methods,” or has not been “reliably applied [to] the principles and methods to the facts of the case.” Fed. R. Evid. 702.

These “exacting standards of reliability,” *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000), require far “more than subjective belief or unsupported speculation,” *Daubert*, 509 U.S. at 590. Courts must ensure the expert “employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

B. The Court’s Three-Stage Inquiry

In the Sixth Circuit, a district court’s inquiry into the propriety of expert testimony proceeds “in three stages.” *United States v. Rios*, 830 F.3d 403, 413 (6th Cir. 2013). The court must determine (1) whether the expert is qualified; (2) whether the expert testimony will assist the trier

of fact to understand the evidence or to determine a fact in issue; and (3) whether the expert testimony is reliable. *See id.* The party offering the expert bears the burden of proof by a preponderance of the evidence at each stage. *United States ex rel. Tenn. Valley Auth. v. 1.72 Acres of Land*, 821 F.3d 742, 749 (6th Cir. 2016).

1. The Expert Must Be Qualified

Under Rule 702, “expert witnesses must be qualified to testify to a matter relevant to the case.” *United States v. Cunningham*, 679 F.3d 355, 379 (6th Cir. 2012). An expert must be qualified by “knowledge, skill, experience, training, or education.” *Id.* (quoting Fed. R. Evid. 702). In determining whether an expert is qualified, “courts do not consider the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.” *Burgett v. Troy-Bilt LLC*, 579 Fed. Appx. 372, 376 (6th Cir. 2014). “Whether a proposed expert’s experience is sufficient to qualify the expert to offer an opinion on a particular subject depends on the nature and extent of that experience.” *Cunningham*, 679 F.3d at 378.

2. The Expert’s Testimony Must Assist the Trier of Fact

Expert testimony is admissible only if it “will assist the trier of fact to understand the evidence or to determine a fact in issue.” *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012) (quoting Fed. R. Evid. 702). The Supreme Court described this requirement as “one of ‘fit.’” *Daubert*, 509 U.S. at 591. In other words, the testimony “must ‘fit’ the facts of the case, that is, there must be a connection between the . . . research or test result being offered and the disputed factual issues in the case in which the expert will testify.” *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000). After all, “scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes.” *Daubert*, 509 U.S. at 591.

Further, expert testimony does not “assist the trier of fact” if it “usurp[s] either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it.” *Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005) (citation omitted); see *Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-cv-144, 2015 WL 13022172, at *11 (S.D. Ohio 2015) (similar). “Examples of ‘expert’ testimony that courts have excluded on this basis include factual narratives and interpretations of conduct or views as to the motivation of parties.” *In re Rezulin*, 309 F. Supp. 2d at 541 (footnotes omitted). Indeed, expert testimony is not admissible if it amounts to “simply rehashing otherwise admissible evidence about which [the expert] has no personal knowledge.” *Highland Capital Mgmt. L.P. v. Schneider*, 379 F. Supp. 2d 461, 469 (S.D.N.Y. 2005), *adopted by* 551 F. Supp. 2d 173, 178 (S.D.N.Y. 2008) (citing cases).

As the Sixth Circuit has explained, “[i]t is not ‘helpful’ when a witness, lay or expert, forms conclusions for a jury that the jurors are competent to reach on their own.” *United States v. Kilpatrick*, 798 F.3d 365, 381 (6th Cir. 2015). Such testimony amounts to impermissible “narrative gloss.” *Id.* (citation omitted); see also *Rheinfrank*, 2015 WL 13022172, at *9 (an expert “cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence”) (quotation source omitted); *In re Welding Fume Prods. Liab. Litig.*, No. 1:03-CV-17000, 2010 WL 7699456, at *41 (N.D. Ohio June 4, 2010) (experts may not offer a “narrative [that] is purely a repetition of the factual allegations in plaintiffs’ complaint, involving nothing technical or scientific”). Thus, “a district court may commit manifest error by admitting expert testimony where the evidence impermissibly mirrors the testimony offered by fact witnesses, or the subject matter of the expert’s testimony is not beyond the ken of the average juror.” *Rios*, 830 F.3d at 413 (internal quotation marks omitted).

3. The Expert's Methodology, Models, and Testimony Must be Reliable

Expert testimony also must be reliable. Under Rule 702, courts must consider whether “the testimony is based upon sufficient facts or data,” whether “the testimony is the product of reliable principles and methods,” and whether “the witness has applied the principles and methods reliably to the facts of the case.” Fed. R. Evid. 702. “Red flags that caution against certifying an expert include reliance on anecdotal evidence, improper extrapolation, failure to consider other possible causes, lack of testing, and subjectivity.” *Newell*, 676 F.3d at 527. The Sixth Circuit has approved consideration of an additional factor: whether the expert prepared his or her opinion “solely for the purposes of litigation.” *Wilden v. Laury Transp., LLC*, 901 F.3d 644, 649 (6th Cir. 2018).

Moreover, expert testimony is not reliable if it is speculative. It is settled that “no matter how good experts’ credentials may be, they are not permitted to speculate.” *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671 (6th Cir. 2010) (reversing admission of expert that was based upon a “string” of speculations). Thus, courts should not admit opinion evidence that is “connected to existing data only by the *ipse dixit* of the expert.” *General Elec. Co. v. Joiner*, 522 U.S. 136, 147 (1997). Expert testimony is inadmissible if “there is simply too great an analytical gap between the data and the opinion offered.” *Id.* Nor should courts admit expert opinion testimony that blindly relies on the opinions of other experts in the same litigation. *See In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig.*, 45 F. Supp. 3d 724, 741 n.6 (N.D. Ohio 2014). With respect to opinions about causation, “the expert’s conclusions regarding causation must have a basis in established fact and cannot be premised on mere suppositions. An expert’s opinion, where based on assumed facts, must find some support for those assumptions in the record.” *McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 801 (6th Cir. 2000).

C. The Court Must Also Consider Whether the Expert Testimony Would Unfairly Prejudice Defendants or Confuse or Mislead the Jury

“Like all evidence, the admissibility of expert testimony is also subject to a . . . balancing of probative value against likely prejudice under Rule 403.” *United States v. Geiger*, 303 Fed. App’x 327, 329 (6th Cir. 2008). The Supreme Court has recognized that expert testimony can “be both powerful and quite misleading because of the difficulty in evaluating it,” so in performing a Rule 403 analysis the district court should “exercise[] more control over experts than over lay witnesses.” *Daubert*, 509 U.S. at 595 (quotation and citation omitted). And courts should likewise “exercise greater care” where the expert’s testimony presents a risk of “subliminally inciting or confusing the jury.” *United States v. Green*, 548 F.2d 1261, 1270 (6th Cir. 1977) (reversing convictions for illegal drug manufacturing after district court admitted DEA expert who provided prejudicial background about the illegal drug trade).

III. GENERAL OVERVIEW OF DEFENDANTS’ MOTIONS

1. Challenges to Plaintiffs’ Experts on Causation

Meredith Rosenthal purports to establish that Defendants’ marketing caused an increase in the number of opioid prescriptions written across the country. Rosenthal’s opinions do not fit the issues in this case, are conceptually flawed, and thus are unhelpful to the trier of fact. The entire basis for her testimony is a fundamentally erroneous and unsupported assumption supplied by Plaintiffs’ counsel that *all* pharmaceutical detailing was unlawful. Specifically, Rosenthal’s regression analysis includes all detailing visits—regardless of whether they were lawful or unlawful, and regardless of the content of detailing—and is thus unable to distinguish between the effects of lawful and unlawful marketing. She also makes her own entirely unsupported assumptions—such as that a detailing visit to a doctor will cause the doctor’s opioid prescribing

to increase exponentially into perpetuity—to give the appearance of a causal relationship between detailing and opioid sales. Her methodology also suffers from numerous other incurable methodological failures that render all of her opinions unreliable and inadmissible. And once Rosenthal’s testimony falls, so fall Plaintiffs’ other causation experts who depend on Rosenthal’s defective opinion.

David Cutler purports to “estimate” the harms caused by Defendants’ marketing and distribution of prescription opioids in the Track One Counties. Cutler’s opinions do not fit the issues of this case, are conceptually flawed, irrelevant, and unhelpful to the trier of fact. First, he fails to distinguish between harms allegedly caused by prescription opioid medications and harms caused by illegal opioids. And because he conducts only national-level regressions of aggregate shipments against mortality associated with *all* illegal and prescription opioids alike, he fails to link any of Defendants’ alleged misconduct to any harms in the Track One Counties. Second, the lynchpin by which Cutler seeks to connect his flawed “average shipment” estimate to alleged Defendant misconduct is either (a) unsupported assumptions provided to him by Plaintiffs’ counsel (in the case of Defendant distributors and pharmacies), or (b) estimates from Professor Rosenthal which are flawed for all the reasons discussed above, and in any event, cannot link the shipments and mortality Cutler analyzed to the alleged misconduct (in the case of Defendant manufacturers). Third, Cutler’s opinions impermissibly aggregate the conduct of all manufacturers, distributors, and pharmacies (*including non-defendants*). Finally, his models contain incurable methodological failures that render his opinions unreliable.

Likewise, Defendants’ motion to exclude certain testimony of **Dr. Jonathan Gruber** shows that his proposed causation analysis is little more than *ipse dixit*. In his graphical analyses,

Gruber measures shipments, opioid-use disorder rates, opioid mortality, and crime across states and counties grouped into the lowest and highest quartiles. He does not, however, measure or analyze relationships between these factors for Cuyahoga and Summit Counties specifically, and he provides no evidence that the same relationships would hold in those counties. Instead, Gruber skips the analytics and simply illustrates the underlying data in a misleading way to try to convince a fact-finder to draw an unsupported causal conclusion. Moreover, Gruber makes no effort to distinguish Defendants' conduct from that of non-party contributors or separate the impacts of illicit opioids. Gruber merely attributes *all* opioid-related harms to Defendants without any underlying analysis, let alone one based on a legitimate, recognized methodology.

Other proposed expert testimony further builds on Rosenthal's erroneous assumption that *all* marketing is unlawful and doubles down by seeking to saddle Defendants with responsibility not only for alleged harm from all opioid prescriptions, but also for all of the attendant costs of the use of illicit street drugs. As explained in Defendants' "**gateway**" **motion**, Dr. Katherine Keyes, Dr. Anna Lembke, and Dr. Jonathan Gruber attempt to establish a causal connection between Defendants' alleged misconduct—which pertains exclusively to lawful, doctor-prescribed opioid medications—and the illegal heroin and fentanyl trade. These experts assert that for some patients, medical use of prescription opioid medications can act as a "gateway," leading (eventually) to heroin and fentanyl use. None of these experts has provided any reliable scientific methodology that establishes any such connection. The scientific literature on the topic, which they purport to survey, focuses almost exclusively on the relationship between unlawful prescription opioid *abuse* and use of street drugs, and even then does not purport to find a causal relationship. Without data

to support their hypothesis, Keyes, Lembke, and Gruber accordingly misinterpret work and articles published by others or simply speculate to assert that medical opioids are a “gateway.”

Defendants also seek to exclude, in a targeted manner, the marketing causation opinions of certain experts. As explained in the motion to exclude the marketing causation testimony of **Drs. Mark Schumacher, Anna Lembke, and Katherine Keyes**, these non-economists purport to give sweeping testimony that Defendants’ marketing caused the “opioid crisis” in Summit and Cuyahoga County, yet have no training or experience in marketing, much less in pharmaceutical marketing and causation, and are unqualified to render their opinions. Beyond that, their causation opinions are unreliable because they employed no methodology (much less a reliable one) to reach those opinions. Remarkably, they conducted no statistical analysis, survey, or other modeling of any marketing, prescribers, or patients in Summit or Cuyahoga County.

2. Challenges to Plaintiffs’ Experts on Liability -- Marketing

Plaintiffs have designated **Dr. David Egilman**—whose opinions have been excluded by state and federal courts repeatedly—as a “catch-all” expert. His report is little more than a factual narrative and legal conclusions based on selective snippets of the record that are not grounded in any personal knowledge, expertise, or reliable methodology. Instead, Egilman’s testimony is precisely the type of narrative “mouthpiece” testimony courts repeatedly have held violates Rules 702 and 403.

Plaintiffs’ proposed experts **Drs. David Kessler** and **Matthew Perri** offer more of the same. Dr. Kessler, who previously served as Commissioner of the FDA when it first approved OxyContin as safe and effective in 1996 and has since spent two decades as a professional witness for plaintiffs’ attorneys suing pharmaceutical companies, provides more improper narrative

testimony, and seeks to impermissibly tell the jury that Defendants violated federal law and regulations. Dr. Perri, a professor in pharmaceutical marketing, similarly engages in improper narrative and contends that Manufacturer Defendants' marketing was improper. Again, numerous cases hold that an expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based on record evidence, cannot give legal conclusions, and cannot testify as to the intent or motives of a defendant. Kessler and Perri's proposed testimony facially violates these baseline prohibitions.

3. Challenges to Plaintiffs' Experts on Liability -- Diversion

Plaintiffs offer **Seth Whitelaw** as an expert on the adequacy of Defendants' suspicious order monitoring programs. Mr. Whitelaw is a food and drug attorney who advises clients on the routine regulations of the Food and Drug Administration. He has no experience with controlled substances, pharmaceutical distribution, the Controlled Substances Act, the Drug Enforcement Administration, or the design, operation, or auditing of suspicious order monitoring programs for controlled substances. Whitelaw is therefore unqualified to provide an opinion on suspicious order monitoring programs. In addition, his opinion is unreliable because it is grounded in an inapposite regulatory framework, the *Federal Sentencing Guidelines* used by federal criminal courts, even though the DEA's representative in this case repudiated the use of the Guidelines for that purpose. Whitelaw also impermissibly seeks to testify to ultimate legal conclusions—namely, whether Defendants' suspicious order monitoring programs complied with the Controlled Substances Act and its corresponding regulations. Whitelaw should be excluded because he is not qualified to be an expert on suspicious order monitoring programs, his opinions are unreliable, and his testimony would usurp the role of the jury.

Plaintiffs also offer **James Rafalski**, a former DEA investigator, as an expert on diversion. Rafalski opines on the adequacy of Defendants' suspicious order monitoring programs and whether Defendants fell short of their legal obligations to identify, report, and stop suspicious orders of prescription opioids. But the anti-diversion obligations Rafalski identifies do not appear anywhere in the Controlled Substances Act or DEA regulations; he simply makes them up. Rafalski's opinions should be excluded for several reasons. First, Rafalski refused to disclose the bases for his so-called legal opinions, citing the DOJ's *Touhy* limitations on this testimony. Second, his methodology for identifying "suspicious orders" is unreliable. He assumes that once a distributor flags a single order from a pharmacy as suspicious, then every subsequent order from that pharmacy is suspicious and should not be fulfilled until the distributor performs due diligence. This assumption leads to Rafalski's sensational conclusion that more than 90% of opioid medications shipped into Cuyahoga and Summit Counties were "suspicious" and that every suspicious order was subsequently diverted. His opinions are based solely on his own unsubstantiated "belief" and do not consider the various factors on which the adequacy of a suspicious monitoring program depends, rendering his methodology unreliable.

Building on Rafalski's unreliable and improper opinions, Plaintiffs also offer **Dr. Craig McCann**, a purported data expert, to apply and report the results of five algorithms created by Rafalski to "flag" orders shipped by certain distributors. McCann's calculations are meaningless and do not fit the facts of the case. They amount to identifying orders that the Distributor Defendants could have identified as potentially suspicious had they used a specific methodology they were under no requirement to use. McCann then compounds the problem by applying an assumption directed by Plaintiffs' counsel that leads him to identify thousands of additional orders

that do not even trigger his algorithms. Plaintiffs' attempt to use those calculations as a measure of Defendants' wrongdoing is without foundation and unfairly prejudicial.

Similarly, Plaintiffs offer the testimony of data analyst **Lacey Keller**, who purports to apply various suspicious order monitoring algorithms to determine how many prescribers and prescriptions Defendants should have flagged as suspicious. But Keller's methodology is unreliable. She admits that her use of the term "suspicious orders" is *not* the same as that term is used in the Controlled Substances Act. She also offers two defendant-specific opinions unique to Janssen and Mallinckrodt that rely on assumptions that are unsupported by anything in the record or reality.

3. Challenges to Plaintiffs' Experts on Damages and Abatement

Plaintiffs' damages expert **Thomas McGuire** offers an opinion that is neither helpful to a jury nor reliable and should be excluded for several reasons. For one, his opinion does not fit this case. McGuire did not calculate alleged damages at all—he calculated only "opportunity costs." McGuire does not assess whether Plaintiffs spent *a single dollar* that they would not have spent absent Defendants' allegedly wrongful conduct. Rather, he assumes that resources the Counties spent addressing opioid-related issues would have been spent elsewhere. McGuire fails to identify any damages at all, let alone damages attributable to Defendants' conduct.

Beyond that, McGuire's damages opinion is unreliable. McGuire's "opportunity cost" calculations depend entirely on subjective, non-replicable "judgments" about whether certain County expenses are fixed or variable. Further, McGuire's estimates do not aid a jury because he fails to apportion damages between Defendants or even categories of Defendants. Perhaps most

fundamentally, McGuire relies on the erroneous opinions of Cutler and Rosenthal, the defects of which render McGuire's estimates unreliable as well.

Finally, Defendants move to exclude Plaintiffs' proposed expert testimony in support of an extraordinary claim for future **abatement activities**. Six experts opine, to varying degrees, on the issue of abatement: Caleb Alexander, Jeffrey Liebman, Katherine Keyes, Scott Wexelblatt, Nancy Young, and Thomas McGuire. These experts opine on abatement plans they believe are needed—that is, various programs, services, and initiatives—to remedy the “opioid crisis.” But the proposed opinions do not fit the facts of this case. These experts do not even evaluate which services *these counties* provide and would need to fund (as opposed to those that would be provided by other governmental or private entities). Moreover, these experts (1) fail to exclude the costs of treating *illegal* opioid users; (2) fail to account for other sources of funding for the programs and services they recommend; and (3) improperly rely on nationwide data instead of considering the specific needs of Cuyahoga and Summit Counties. The opinions also are unreliable, as they are based on an inordinate amount of speculation and also leave no way to test the validity of their methodologies.

For these, and the numerous other reasons set forth in the accompanying motions, the admission of Plaintiffs' proposed expert testimony on causation, liability, damages and abatement violates Rules 702 and 403, would taint the entire trial, and constitute reversible error.

Date: June 28, 2019

Respectfully submitted,

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² Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their pending motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion as a result of the Court's deadline to file dispositive and Daubert motions, and, thus, they do not waive and expressly preserve their pending personal jurisdiction challenges.

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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